

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS **EPASERIES 361**

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

MEMORANDUM

DATE:

June 7, 1999

SUBJECT:

Fipronil - Acute and Chronic Dietary Exposure Analyses. Chemical#: 129121.

DP Barcode: D255832. Case #: 291825. Submission #: S560375.

TO/FROM:

Susie Chun, Chemist

Registration Action Branch 1 Health Effects Division

THROUGH:

Mike Doherty, Chemist Hucha

Dave Soderberg, Chemist

Dietary Exposure Science Advisory Council

Melba Morrow, D.V.M., Branch Senior Scientist

Registration Action Branch 1

Health Effects Division

Action Requested

Provide an estimate of the dietary exposure and associated risks for fipronil resulting from an emergency exemption (Section 18) request in/on cottonseed RACs (98MS0011). The proposed use will also affect existing tolerances for residues in meat, poultry, and milk.

The following are the proposed tolerances:

| Cottonseed | 0.5 ppm |
|--------------------------|----------|
| Cotton Gin Trash | 10.0 ppm |
| Meat Byproducts* (except | 0.3 ppm |
| liver) | |
| Meat* | 0.5 ppm |
| Fat* | 3.6 ppm |
| Liver* | 1.1 ppm |

^{*} of cattle, sheep, goats, and horses

| 0.07 ppm |
|----------|
| 0.06 ppm |
| 0.11 ppm |
| 0.04 ppm |
| 12.0 ppm |
| |

Executive Summary

The FQPA Safety Factor was removed (i.e., reduced to 1x) for acute and chronic dietary exposures. Therefore the acute and chronic population adjusted doses (aPAD and cPAD, respectively) are the same values as the acute and chronic reference doses (aRfD and cRfD), respectively. The PAD is a modification of the acute RfD or chronic RfD to include the FQPA Safety Factor.

For the acute dietary analysis, an aPAD of 0.02 mg/kg/day (incorporating 10x for interspecies extrapolation, 10x for intraspecies extrapolation, and 1x FQPA Safety Factor) was used. The Tier 2 acute dietary analysis for fipronil is a partially refined estimate of dietary exposure with the use of anticipated residues (ARs) for blended commodities and 100 percent crop treated (%CT). The percent aPADs were below HED's level of concern (<100 % aPAD) at the 95th percentile for the U.S. population and all subgroups. The results of this analysis indicate that the acute dietary risk associated with the S18 use of fipronil on cottonseed is below HED's level of concern.

For the chronic dietary analysis, a cPAD of 0.0002 mg/kg/day (incorporating 10x for interspecies extrapolation, 10x for intraspecies extrapolation, and 1x FQPA Safety Factor) was used for fipronil (+MB45950 and MB46136) and a cPAD of 0.00002 mg/kg/day (incorporating 10x for interspecies extrapolation, 10x for intraspecies extrapolation, and 1x FQPA Safety Factor) was used for the fipronil photodegradate, MB46513. The Tier 3 chronic dietary analyses for fipronil and MB46513 are more refined estimates with the use of anticipated residues (ARs) and %CT or %Anticipated market share information. Percent CT information was used for cottonseed RACs. Anticipated market share information was used for rice and corn RACs. However, the chronic dietary analyses are still an over-estimation of dietary exposure. Further refinements would entail the use of monitoring data (if available) for all commodities. The percent cPADs were below HED's level of concern for the U.S. population and all subgroups. The results of this analysis indicate that the chronic dietary risk associated with the S18 use of fipronil on cottonseed RACs is below HED's level of concern.

Note: Since the revised ARs (incorporating cottonseed RACs) will be applicable in support of this S18 action only, this dietary analysis is applicable only to this Section 18. Should any other states request approval for use of fipronil on cottonseed RACs under FIFRA Section 18, the percent crop treated will have to be updated and the ARs adjusted accordingly. Consequently, a new dietary exposure analysis will have to be completed.

Toxicological Endpoints

The Hazard Identification Assessment Review Committee (HIARC) met on July 10, 1997 to select appropriate endpoints for acute dietary and short-, intermediate-, and long-term occupational exposure (dermal and inhalation) for fipronil and on December 9, 1997 to select appropriate endpoints for acute dietary and short-, intermediate-, and long-term occupational exposure (dermal and inhalation) for the fipronil photodegradate MB46513. On January 22, 1998, the HIARC reassessed the potential sensitivity of infants and children and to discuss the uncertainty factors (UF) and/or Margins of Exposure (MOE) for both the parent, fipronil and the photodegradate MB46513. On April 22, 1998, the HIARC met again to re-evaluate the

endpoints for fipronil and its photodegradate based on new and re-evaluated data (Memo, J. Rowland and M. Copley, HED Doc. No. 012607, 5/7/98). The conclusions, which superseded all conclusions in previous HIARC documents, are summarized in Tables 1 and 2.

Table 1- Toxicological Doses and Endpoints for Fipronil (Parent)

| EXPOSURE SCENARIO | | | | |
|----------------------|--|--|---------------------------|--|
| Acute (Dietary) | NOAEL = 2.5 mg/kg/day UF = 100 FQPA SF = 1 | Decreased hind leg splay in male and female rats in an acute neurotoxicity study in rats. | Acute neurotoxicity | |
| | | Acute RfD = 0.025 mg/kg/day Acute PAD =0.025 mg/kg/day | | |
| Chronic (Dietary) | NOAEL = 0.019 mg/kg/day UF = 100 FQPA SF=1 | Increased incidence of seizures and death, alterations in clinical chemistry (protein) and † TSH, ↓ T4. | Chronic/onco rat study | |
| | | Chronic RfD = 0.0002 mg/kg/day Chronic PAD = 0.0002 mg/kg/day | | |
| Cancer (Dietary) | NA | Group C - Possible Human Carcinogen (increases in thyroid follicular cell tumors with fipronil (M&F)). Use RfD to estimate human risk. | | |

Table 2. Toxicological Doses and Endpoints for photodegradate (MB46513)

| EXPOSURE SCENARIO | Dose (mg/kg/day) | ENDPOINT AND TOXICOLOGICAL EFFECT | STUDY | | |
|----------------------|---|--|---------------------|--|--|
| Acute (Dietary) | NOAEL = 2.0 mg/kg/day UF = 100 FQPA SF = 1 | Decreased locomotor activity as well as decreases in hindlimb splay and rectal temperature | Acute neurotoxicity | | |
| | | RfD = 0.02 mg/kg/day $PAD = 0.02 mg/kg/day$ | | | |
| Chronic (Dietary) | *Adjusted NOAEL = 0.0019 mg/kg/day UF = 100 FQPA SF = 1 | Increased incidence of seizures and death, alterations in clinical chemistry (protein) and † TSH, † T4. (fipro | | | |
| | Chronic RfD = 0.00002 mg/kg/day Chronic PAD= 0.00002 mg/kg/day | | | | |
| Cancer (Dietary) | NA | Group C - Possible Human Carcinogen (increases in thyroid follicular cell tumors with fipronil (M&F)). Use RfD to estimate human risk. | | | |

^{• =} Adjusted NOAEL obtained by dividing the actual NOAELs established in the studies conducted with the parent compound fipronil and potency adjustment factor (PAF) of 10. A PAF of 10 was determined by the HIARC based on the toxicity profiles of the **photodegradate MB41513** and **fipronil**.

Cancer

Fipronil has been classified by the HED Cancer Peer Review Committee (document dated July 18, 1997) as a Group C - Possible Human Carcinogen, based on increases in thyroid follicular cell tumors in both sexes of the rat, which were statistically significant by both pair-wise and trend analyses. There are no cancer studies with the photodegradate MB46513. The RfD methodology should be used to estimate human risk because the thyroid tumors appear to be related to a disruption in the thyroid-pituitary status. There was no apparent concern for mutagenicity (no mutagenic activity).

FQPA Recommendation

The HIARC recommended that the 10 x factor to account for enhanced sensitivity of infants and children (as required by FQPA) should be removed. The HIARC concluded that the apparent increased susceptibility in the developmental neurotoxicity study was not supported by the overall weight-of-the-evidence (including no evidence for increased susceptibility in the developmental and reproduction studies) from the fipronil data base (Memo, J. Rowland and M. Copley, HED Doc. No. 012607, 5/7/98).

The FQPA Safety Factor Committee (SFC) met on 27-APR-1998. The FQPA SFC recommended that the **10x factor** for enhanced sensitivity to infants and children (as required by FQPA) should be **removed** for fipronil and its photodegradate, MB46513 (Memo, B. Tarplee and J. Rowland, HED. Doc. No. 012619, 5/12/98).

Since the FQPA SF is removed (i.e. reduced to 1x), the aPAD and the cPAD are the same as the acute and chronic RfDs, respectively. The PAD is a modification of the aRfD or cRfD to include the FQPA Safety Factor or:

$$PAD = \frac{RfD}{FOPA SF}$$

Residue Information

The HED Metabolism Committee, in a meeting held on May 28, 1997, determined that the fipronil residues of concern for the tolerance expression and dietary risk assessment in plants and animals are the parent and its metabolites MB 46136 and MB45950. The Metabolism Committee also concluded that residue data for metabolite MB46513 will be required for crops for which metabolism data indicate that this metabolite comprises a significant portion of the total radioactive residue (i.e., rice, potatoes, and rotational crops) (Memo, D236164, R. Loranger, 6/5/97).

Metabolite MB46513 was identified as a significant component in/on rice commodities. HED concurred with the petitioner that the residues of concern in rice are fipronil and its metabolites MB45950, MB46136, and MB46513. MB46513 was therefore added to the tolerance expression. Cottonseed RAC residue data also was submitted with data including MB46513. Corn residue data indicate that this metabolite does not comprise a significant portion of the total radioactive residue.

Currently the tolerance expression in the 40 CFR includes fipronil and the 3 metabolites, MB45950, MB46136, and MB46513.

Anticipated Residue Information

Anticipated residues (ARs) were calculated and incorporated a dietary exposure analysis, which was completed with the Dietary Risk Evaluation System (DRES), in support of a tolerance on rice (PP#7F4832, Memo, D239007, G. Kramer, et. al, 1/16/98; Memo, D241676, G. Kramer, et. al., 5/22/98.)

With the proposed use on cottonseed RACs, those ARs need to be revised. The current S18 action results in increased fipronil (+metabolites) residues in animal feed items. Therefore, it is necessary to recalculate the ARs for animal commodities. Should any other states request approval for use of fipronil on cottonseed RACs under FIFRA Section 18, the maximum percent crop treated will have to be updated and the ARs adjusted accordingly.

The revised ARs (incorporating cottonseed RACs) will be applicable in support of this S18 action only.

Anticipated residue (AR) information based on field trial data (Memo, D255833, S. Chun, 5/19/99), % CT information (estimated for this S18 only), and % Anticipated Market Share information were used.

Tables 1, 2, and 3 present the ARs used in the dietary exposure analyses.

Note: The Hazard Identification Assessment Review Committee (HIARC) chose a dose and endpoint each for fipronil (including the metabolites MB45950 and MB46136) and for MB46513. The acute reference dose (aRfD) selected for MB46513 was less than the aRfD for fipronil. MB46513 is considered more acutely toxic than the parent. Since the FQPA SFC determined to remove the SF (i.e. reduced to 1x) the aRfD is the same as the aPAD for the MB46513 photodegradate. A tier 2 acute dietary analysis will be done with MB46513's aPAD, incorporating fipronil (+2 metabolites). If further refinements in the acute dietary risk assessment are required in the future, separate acute dietary exposure analyses may have to be performed for MB 46513 and fipronil (+2 metabolites) separately.

Table 1. Summary of Fipronil + MB 46136 + MB 45950 + MB46513 Residues for Tier 2 Acute
Dietary Risk Assessment

| Dictary Rest Placesment | | | | | | |
|--|--|--|--|--|--|--|
| Commodity | AR to Use in Acute Dietary Exposure Analysis (ppm) | | | | | |
| Corn Grain ^{1, 6} | 0.015 | | | | | |
| Includes processed commodities | | | | | | |
| Rice Grain ^{2, 6} | 0.021 | | | | | |
| Includes processed commodities | | | | | | |
| Excludes wild rice | | | | | | |
| Cottonseed 3, 6 | 0.011 | | | | | |
| Includes processed commodities | | | | | | |
| Meat ⁴ | 0.089 | | | | | |
| Liver ⁴ | 0.23 | | | | | |
| Meat by-products (except liver) ³ | 0.058 | | | | | |
| Fat ⁴ | 0.78 | | | | | |
| Milk Fat ⁵ | 1.0 | | | | | |
| Hog Meat | 0.0024 | | | | | |
| Hog Liver | 0.0063 | | | | | |
| Hog Meat by-products (except liver) | 0.0016 | | | | | |
| Hog Fat | 0.021 | | | | | |
| Poultry meat | 0.0030 | | | | | |
| Poultry meat by-products | 0.010 | | | | | |
| Poultry fat | 0.028 | | | | | |
| Eggs | 0.016 | | | | | |

Since residues do not concentrate in processed commodities of corn, the anticipated residue of 0.015 ppm should be used for such commodities in the dietary exposure analysis (i.e. corn oil, meal, etc.).

Since residues do not concentrate in processed commodities of rice, the anticipated residue of 0.021 ppm should be used for such commodities in the dietary exposure analysis (i.e. flour, etc.).

Since residues do not concentrate in processed commodities, the AR of 0.011 should be used for such commodities in the dietary exposure analysis (i.e., cotton meal, cottonseed oil).

These anticipated residues should also be used for meat, fat and meat by-products of horses, goats and sheep in the dietary exposure analysis.

All residues in milk are assumed to concentrate in fat, a value of 0 ppm should be used for other milk fractions

⁶ Blended commodities will use the average field trial value.

Chronic

Table 2. Summary of Fipronil + MB 46136 + MB 45950 ARs for Tier 3 Chronic Dietary Risk Assessment

| Commodity | % CT or %Anticipated Market Share | AR to use in Chronic Dietary Exposure Analysis ⁶ (ppm) |
|---|---|---|
| Corn Grain ¹ | 7 | 0.015 |
| Rice Grain ² Includes processed commodities Excludes wild rice | 11 | 0.015 |
| Cottonseed ³ | 3.6 | 0.0060 |
| Meat ⁴ | | 0.00074 |
| Liver ⁴ | | 0.0020 |
| Meat by-products (except liver) ⁴ | | 0.00048 |
| Fat ⁴ | | 0.0066 |
| Milk Fat ⁵ | do 40 40 50 | 0.017 |
| Hog Meat | | 0.00017 |
| Hog Liver | ~~~ | 0.00044 |
| Hog Meat by-products (except liver) | | 0.00011 |
| Hog Fat | | 0.0015 |
| Poultry meat | | 0.00021 |
| Poultry meat by-products | | 0.00071 |
| Poultry fat | | 0.0019 |
| Eggs | | 0.0011 |

Since residues do not concentrate in processed commodities of corn, the anticipated residue of 0.001 ppm should be used for such commodities in the DEEMTM analysis (i.e. corn oil, meal, etc.) except corn sugar for which processing data are not available.

Since residues do not concentrate in processed commodities of rice, the anticipated residue of 0.015 ppm should be used for such commodities in the DEEM TM analysis (i.e. flour, etc.).

- These anticipated residues should also be used for meat, fat and meat by-products of horses, goats and sheep in the DEEM™ analysis.
- All residues in milk are assumed to concentrate in fat, a value of 0 ppm should be used for other milk fractions
- The ARs in the RACs do not incorporate %CT or % Anticipated Market Share.

Since residues do not concentrate in processed commodities of cottonseed, the anticipated residue of 0.0016 ppm should be used for such commodities in the DEEM[™] analysis (i.e. cotton meal, cottonseed oil, etc.).

Table 3. Summary of MB46513 ARs for Tier 3 Chronic Dietary Risk Assessment

| Commodity | % CT or %Anticipated Market Share | AR to use in Chronic Dietary Exposure Analysis ⁶ (ppm) |
|--|---|---|
| Corn Grain ¹ | 7 | 0 |
| Includes processed commodities | | |
| Rice Grain ² | 11 | 0.0050 |
| Includes processed commodities | | |
| Excludes wild rice | | |
| Cottonseed ³ | 3.6 | 0.0047 |
| Meat ⁴ | w | 0.000069 |
| Liver ⁴ | | 0.00018 |
| Meat by-products (except liver) ⁴ | | 0.000045 |
| Fat ⁴ | | 0.00061 |
| Milk Fat ⁵ | | 0.0019 |
| Hog Meat | | 0.000035 |
| Hog Liver | | 0.000092 |
| Hog Meat by-products (except liver) | | 0.000023 |
| Hog Fat | | 0.00031 |
| Poultry meat | | 0.000010 |
| Poultry meat by-products | | 0.000036 |
| Poultry fat | | 0.000098 |
| Eggs | | 0.000055 |

MB46513 is not a metabolite found in corn. Therefore, an AR of 0 ppm can be used for corn RACs.

For cottonseed, percent crop treated was estimated from <u>Agricultural Statistics</u>, 1995-1996. According to this source, a total of 137,201,000 acres of cottonseed was planted in 1994 in the continental United States. This S18 request is for a total of 500,000 acres in Mississippi. Therefore, *for this S18 action only*, the maximum percent crop treated is 3.6% [(acreage to be treated ÷ acres planted in 1994) x 100].

For the acute dietary analysis, tolerance level residues, ARs for blended commodities, 100% CT, and an aPAD of 0.02 mg/kg/day (MB46513's) were used.

For the chronic dietary analysis, ARs based on field trial data (Memo, D255833, S. Chun, D243318, in preparation), % CT information for cottonseed RACS, and % Anticipated Market Share Information for rice and corn RACS were used. A cPAD of 0.0002 mg/kg/day was used

Since residues do not concentrate in processed commodities of rice, the anticipated residue of 0.005 ppm should be used for such commodities in the DEEM[™] analysis (i.e. flour, etc.).

Since residues do not concentrate in processed commodities of cottonseed, the anticipated residue of 0.0016 ppm should be used for such commodities in the DEEM[™] analysis (i.e. cotton meal, cottonseed oil, etc.).

These anticipated residues should also be used for meat, fat and meat by-products of horses, goats and sheep in the DEEM™ analysis.

All residues in milk are assumed to concentrate in fat, a value of 0 ppm should be used for other milk fractions

The ARs in the RACs do not incorporate %CT or % Anticipated Market Share.

for fipronil (+ MB45950 and MB46136) and a cPAD of 0.00002 mg/kg/day was used for MB46513. The registrant submitted a projected market share percent of 11% for rice and 7% for corn. The Biological and Economics Analysis Division (BEAD) has re-verified these values [personal communication to S. Chun from A. Halvorson, 5/19/99]. Therefore, these values were used in the chronic dietary analysis

Since there is no concentration in processed commodities for rice, corn, or cottonseed, the ARs in the RAC will be used in their respective processed commodities.

Results

The Dietary Exposure Evaluation Model (DEEM[™]) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-92 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Summaries of the residue information used in the acute, chronic (fipronil, MB45950, MB46136) and chronic (MB46513) dietary exposure analyses are attached (Attachments 1, 3, and 5).

Acute Dietary Exposure Analysis

The acute dietary exposure analysis estimates the distribution of single-day exposures for the U.S. population and certain subgroups and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of fipronil (+ MB45950, MB46136, and MB46513) for the commodities on which fipronil (+ MB45950, MB46136, and MB46513) is used.

The FQPA SFC removed the 10x factor (i.e., reduced to 1x) resulting in an aPAD of 0.02 mg/kg/day. HED's level of concern is for acute dietary exposures greater than 100% aPAD. The acute dietary exposure analysis was performed for the U.S. population and 26 subgroups. A summary with all population subgroups is attached (Attachment 2).

Dietary exposures and associated acute dietary risk are shown in Table 1. Besides the U.S. population, the subgroups included in Table 1 represent all children's subgroups and the highest dietary exposures for their respective subgroups (i.e., females and males).

Table 1. - Acute Dietary Exposure Results

| | 95 th Percentile | | 99 th Perce | ntile | 99.9 th Percentile | | |
|--------------------------------|-----------------------------|-----------|-------------------------|-----------|-------------------------------|-----------|--|
| Subgroups | Exposure (mg/kg/day) | % aPAD | Exposure (mg/kg/day) | % aPAD | Exposure (mg/kg/day) | % aPAD | |
| U.S. Population | 0.001717 | 9 | 0.002911 | 15 | 0.004482 | 22 | |
| All infants (<1 year) | 0.002869 | 14 | 0.004338 | 22 | 0.006288 | 31 | |
| Nursing infants (< 1 year) | 0.001063 | 5 | 0.003089 | 15 | 0.003467 | 17 | |
| Non-nursing infants (< 1 year) | 0.003223 | 16 | 0.004491 | 22 | 0.006049 | 30 | |
| Children (1-6 years old) | 0.003244 | 16 | 0.004382 | 22 | 0.005793 | 29 | |
| Children (7-12 years old) | 0.002114 | 11 | 0.003056 | 15 | 0.004438 | 22 | |
| Females (13-19 yrs/np/nn) | 0.001309 | 7 | 0.002181 | 11 | 0.003225 | 16 | |
| Males (13-19 years old) | 0.001461 | 7 | 0.001985 | 10 | 0.002982 | 15 | |

Chronic Dietary Analysis

The chronic DEEM[™] dietary exposure analysis used mean consumption (3 day average). The FQPA SFC removed the 10x factor (i.e., reduced to 1x) resulting in a cPAD of 0.0002 mg/kg/day for fipronil (+MB45950 and MB46136) and 0.00002 mg/kg/day for MB46513. HED's level of concern is for chronic dietary exposures greater than 100% cPAD. Dietary exposures for the U.S. general population and other subgroups are presented in Tables 2 and 3. The other subgroups included represent the highest dietary exposures for their respective subgroups (i.e., infants, children, females, and males).

Table 2. - Chronic Dietary Exposure Results (Fipronil, MB45950, and MB46136)

| Subgroups | Exposure (mg/kg/day) | % cPAD |
|-----------------------------|-------------------------|--------|
| U.S. Population (48 states) | 0.000010 | 5 |
| Non-nursing Infants | 0.000014 | 7 |
| Children (1 - 6 years old) | 0.000027 | 13 |
| Females (13-19, np/nn) | 0.000009 | 4 |
| Males (13-19 years old) | 0.000011 | 6 |

Table 3. - Chronic Dietary Exposure Results (MB46513)

| Subgroups | Subgroups Exposure (mg/kg/day) | | | |
|-----------------------------|--------------------------------|-----|--|--|
| U.S. Population (48 states) | 0.000001 | 5 | | |
| Non-nursing Infants | 0.000002 | 8 | | |
| Children (1 - 6 years old) | 0.000003 | 13 | | |
| Females (13-19, np/nn) | 0.000001 | 4 . | | |
| Females (13+, nursing) | 0.000001 | 4 | | |
| Males (13-19 years old) | 0.000001 | 5 | | |

Complete chronic dietary exposure analyses are attached (Attachments 4 and 6).

Conclusions

The Tier 2 acute dietary analysis for fipronil is a somewhat conservative estimate of dietary exposure with the use of ARs for blended commodities and 100 percent of the commodities assumed to be treated. Also, the combining of fipronil with all 3 metabolites using the lower aPAD reflects a conservative estimate. The percent aPADs were below HED's level of concern at the 95th percentile for the U.S. population and all subgroups with the highest exposure of 16% aPAD in the subgroup children (1-6 years old). The results of this analysis indicate that the acute dietary risk associated with the proposed use of fipronil on cottonseed RACs is below HED's level of concern.

The Tier 3 chronic dietary analyses for fipronil (+ 2 metabolites) and MB46513 are more refined estimates with the use of ARs and %CT information. Further refinements would entail the use of monitoring data for all commodities. The percent cPADs (fipronil + 2 metabolites) were below HED's level of concern for the U.S. population and all subgroups with the highest exposure of 13% cPAD in the subgroup children (1-6 years old). The percent cPADs (MB46513) were below HED's level of concern for the U.S. population and all subgroups with the highest exposure of 13% cPAD in the subgroup children (1-6 years old). The results of these analyses indicate that the chronic dietary risk associated with the proposed use of fipronil on cottonseed RACs is below HED's level of concern.

Attachment 1: Residue File -Acute

Attachment 2: Acute DEEM[™] analysis - (S. Chun, 5/20/99)

Attachment 3: Residue File - Chronic (Fipronil, MB45950, and MB46136)

Attachment 4: Chronic DEEM[™] analysis (Fipronil, MB45950, and MB46136) [S. Chun, 5/20/99]

Attachment 5: Residue File - Chronic (MB46513)

Attachment 6: Chronic DEEM[™] analysis (MB46513) [S. Chun, 5/20/99]

cc(with attachments): S. Chun (RAB1); M. Sahafeyan (CEB1), PP# 99MS0011 RDI: Dietary Exposure SAC [D. Soderberg (5/28/99), M. Doherty (6/2/99)]; M. Morrow (6/7/99) S. Chun:806R:CM#2:(703)305-2249:7509C:RAB1

Attachment 1: Residue Information - Acute

Filename: C:\deem\resdata\129121a.r96

Chemical name: Fipronil

RfD(Chronic): .0002 mg/kg bw/day NOEL(Chronic): .019 mg/kg bw/day

RfD(Acute): .02 mg/kg bw/day NOEL(Acute): 2 mg/kg bw/day

Date created/last modified: 06-02-1999/06:19:09/8 Program ver. 6.77

Comment: FQPA SF=1, UF=100, therefore RfD=PAD; Fipronil (+3 metabolites)

| | | | - | | | | |
|------|------|--------------------------------|--------------|-----|---------|-------|--------------------------|
| Food | Crop | | RESIDUE | RDF | Adj.Fac | tors | Comment |
| Code | Grp | Food Name | (ppm) | | #1 | | |
| | | | | | | | |
| 291 | 0 | Cottonseed-meal | 0.011000 | 0 | 1.000 | 0.036 | New, S18, AR |
| 290 | 0 | Cottonseed-oil | 0.011000 | 0 | 1.000 | 0.036 | New, S18, AR |
| 323 | М | Beef-dried | 0.089000 | 0 | 1.920 | 1.000 | New, $TLT + 0.46$, AR |
| 324 | M | Beef-fat w/o bones | 0.780000 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 325 | М | Beef-kidney | 0.058000 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 327 | М | Beef-lean (fat/free) w/o bones | 0.089000 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR |
| 326 | M | Beef-liver | 0.230000 | 0 | 1.000 | 1.000 | New, TLT + 1.0, AR |
| 321 | M | Beef-meat byproducts | 0.058000 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 322 | M | Beef-other organ meats | 0.058000 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 330 | M | Goat-fat w/o bone | 0,780000 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 331 | M | Goat-kidney | 0.058000 | 0 | 1,000 | | New, TLT + 0.26, AR |
| 333 | M | Goat-lean (fat/free) w/o bone | 0.089000 | 0 | 1.000 | 1.000 | New, $TLT + 0.46$, AR |
| 332 | M | Goat-liver | 0.230000 | 0 | 1.000 | | New, TLT + 1.0, AR |
| 328 | M | Goat-meat byproducts | 0.058000 | 0 | 1.000 | | New, TLT + 0.26, AR |
| 329 | M | Goat-other organ meats | 0.058000 | 0 | 1.000 | | New, TLT + 0.26, AR |
| 334 | M | Horsemeat | 0.089000 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR |
| 344 | М | Pork-fat w/o bone Pork-kidnev | 0.021000 | 0 | 1.000 | | New, TLT +0.03 ppm |
| 345 | М | Pork-kidney | 0.001600 | 0 | 1.000 | 1.000 | |
| 347 | M | Pork-lean (fat free) w/o bone | 0.002400 | 0 | 1.000 | 1.000 | AR |
| 346 | M | Pork-liver | 0.006300 | 0 | 1.000 | 1.000 | AR |
| 342 | М | Pork-meat byproducts | 0.001600 | 0 | 1.000 | 1.000 | |
| 343 | M | Pork-other organ meats | 0.001600 | 0 | 1.000 | 1.000 | AR |
| 338 | M | Sheep-fat w/o bone | | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 339 | М | Sheep-kidney | 0.058000 | 0 . | 1.000 | | New, TLT + 0.26, AR |
| 341 | М | Sheep-lean (fat free) w/o bone | 0.089000 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR |
| 340 | M | Sheep-liver | 0.230000 | 0 | 1.000 | 1.000 | New, $TLT + 1.0$, AR |
| 336 | M | Sheep-meat byproducts | 0.058000 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 337 | М | Sheep-other organ meats | 0.058000 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 429 | M | Veal-dried | 0.089000 | 0 | 1.920 | | New, TLT + 0.46, AR |
| 424 | М | Veal-fat w/o bones | 0.780000 | 0 | 1.000 | | New, TLT + 3.2 ppm, AR |
| 426 | М | Veal-kidney | 0.058000 | O | 1.000 | | New, TLT + 0.26, AR |
| | | _ | | | | | |

| 425 | М | Veal-lean (fat free) w/o bones | 0.089000 | 0 | 1.000 | 1.000 New, | TLT + | 0.46. | AR |
|-----|----|----------------------------------|----------|---|-------|------------|-------|-------|----|
| 427 | M | Veal-liver | 0.230000 | 0 | 1.000 | 1.000 New, | | • | |
| 430 | М | Veal-meat byproducts | 0.058000 | 0 | 1.000 | 1.000 New. | | • | |
| 428 | M | Veal-other organ meats | 0.058000 | 0 | 1,000 | 1.000 New, | | • | |
| 366 | Р | Chicken-byproducts | 0.010000 | 0 | 1.000 | 1.000 New, | | • | |
| 368 | P | Chicken-fat w/o bones | 0.028000 | 0 | 1.000 | 1.000 New, | | | |
| 367 | P | Chicken-giblets(liver) | 0.010000 | 0 | 1.000 | 1.000 New, | | | |
| 385 | Р | Chicken-giblets (excl. liver) | 0.010000 | 0 | 1.000 | 1.000 New, | | | |
| 369 | Р | Chicken-lean/fat free w/o bones | 0.003000 | 0 | 1.000 | 1.000 AR | | • | |
| 364 | Р | Eggs-white only | 0.016000 | 0 | 1.000 | 1.000 New, | TLT + | 0.03, | AR |
| 363 | Р | Eggs-whole | 0.016000 | 0 | 1.000 | 1 000 New, | TLT + | 0.03 | AR |
| 365 | P | Eggs-yolk only | 0.016000 | 0 | 1.000 | 1.000 New, | | | |
| 362 | P | Poultry-other-fat w/o bones | 0.028000 | 0 | 1.000 | 1.000 New, | TLT + | 0.06 | AR |
| 361 | P | Poultry-other-giblets(liver) | 0.010000 | 0 | 1.000 | 1.000 New, | TLT + | 0.02, | AR |
| 360 | Р | Poultry-other-lean (fat free) w/ | 0.003000 | 0 | 1.000 | 1.000 AR | | · | |
| 355 | P | Turkey-byproducts | 0.010000 | 0 | 1.000 | 1.000 New, | TLT + | 0.06, | AR |
| 357 | Р | Turkeyfat w/o bones | 0.028000 | 0 | 1.000 | 1.000 AR | | | |
| 356 | Р | Turkey-giblets (liver) | 0.010000 | 0 | 1.000 | 1.000 New, | TLT + | 0.02, | AR |
| 358 | Р | Turkey- lean/fat free w/o bones | 0.003000 | 0 | 1.000 | 1.000 AR | | | |
| 449 | P | Turkey-other organ meats | 0.010000 | 0 | 1.000 | 1.000 New, | TLT + | 0.02, | AR |
| 319 | D | Milk-fat solids | 1.000000 | 0 | 1.000 | 1.000 New, | TLT + | 10.5, | AR |
| 267 | 15 | Corn grain-bran | 0.015000 | 0 | 1.000 | 0.070 AR | | | |
| 266 | 15 | Corn grain-endosperm | 0.015000 | 0 | 1.000 | 0.070 AR | | | |
| 289 | 15 | Corn grain-oil | 0.015000 | 0 | 1.000 | 0.070 AR | | | |
| 268 | 15 | Corn grain/sugar/hfcs | 0.015000 | 0 | 1.500 | 0.070 AR | | | |
| 388 | 15 | Corn grain/sugar-molasses | 0.015000 | 0 | 1.500 | 0.070 AR | | | |
| 408 | 15 | Rice-bran | 0.021000 | 0 | 1.000 | 0.110 AR | | | |
| 271 | 15 | Rice-milled (white) | 0.021000 | 0 | 1.000 | 0.110 AR | | | |
| 270 | 15 | Rice-rough (brown) | 0.021000 | 0 | 1.000 | 0.110 AR | | | |

Attachment 2: Acute Dietary Exposure Analysis

U.S. Environmental Protection Agency

DEEM ACUTE analysis for FIPRONIL

Residue file: 129121a.r96

Adjustment factor #2 NOT used.

Analysis Date: 06-02-1999/06:48:44

Residue file dated: 06-02-1999/06:34:06/8

Acute Reference Dose (aRfD) = 0.020000 mg/kg body-wt/day

NOEL (Acute) = 2.000000 mg/kg body-wt/day

Run Comment: FQPA SF=1, UF=100, therefore RfD=PAD; Fipronil (+3 metabolites)

Summary calculations:

| Exposure % aRfD MOE Exposure % aRfD MOE Exposure % aRfD MOE U.S. pop - all seasons: 0.001717 8.59 1164 0.002911 14.56 687 0.004482 22.41 4 U.S. pop - spring season: | E 146 133 |
|--|---------------------|
| 0.001717 8.59 1164 0.002911 14.56 687 0.004482 22.41 4 | |
| | |
| U.S. DOU - SDLIBU SEASUH. | 133 |
| 0.001742 8.71 1147 0.003193 15.97 626 0.004608 23.04 4 | |
| U.S. pop - summer season: 0.001803 9.02 1109 0.002869 14.34 697 0.004453 22.26 4 | 149 |
| U.S. pop - autumn season: 0.001791 8.95 1116 0.002958 14.79 676 0.004533 22.67 4 | 441 |
| U.S. pop - winter season: | 525 |
| Northeast region: | |
| 0.001771 8.85 1129 0.003178 15.89 629 0.005012 25.06 3 | 399 |
| Midwest region: | |
| | 167 |
| Southern region: 0.001628 8.14 1228 0.002771 13.85 721 0.004364 21.82 4 | 158 |
| Western region: | 100 |
| · · · · · · · · · · · · · · · · · · · | 473 |
| Hispanics: | 413 |
| Non-hispanic whites: | |
| | 459 |
| Non-hispanic blacks: | |
| | 451 |
| | 465 |
| | 318 |
| Nursing infants (<1 year): | |
| | 576 |
| Non-nursing infants (<1 yr): 0.003223 16.12 620 0.004491 22.45 445 0.006049 30.25 3 | 330 |
| Children (1-6 years): | |
| 0.003244 16.22 616 0.004382 21.91 456 0.005793 28.96 3 Children (7-12 years): | 345 |
| - | 450 |
| Females (13+/preg/not nsg): | 150 |
| | 056 |
| Females (13+/nursing): | |
| | 007 |
| Females (13-19 yrs/np/nn): | |
| 0.001309 6.54 1528 0.002181 10.90 917 0.003225 16.13 6 Females (20+ years/np/nn): | 520 |
| 0.000910 4.55 2197 0.001360 6.80 1470 0.002125 10.63 9 | 941 |
| Females (13-50 years): 0.001046 5.23 1911 0.001553 7.77 1287 0.002741 13.70 7 | 729 |
| Males (13-19 years): 0.001461 7.31 1368 0.001985 9.92 1007 0.002982 14.91 6 | -70 |
| 0.001461 7.31 1368 0.001985 9.92 1007 0.002982 14.91 6 Males (20+ years): | 670 |
| 0.001105 5.53 1809 0.001654 8.27 1208 0.002689 13.44 7 | 743 |
| Seniors (55+): | |
| | 983 |
| Pacific Region: 0.001656 8.28 1207 0.002758 13.79 725 0.003825 19.12 5 | 522 |

Attachment 3: Residue Information - Chronic (Fipronil + 2 metabolites)

Filename: C:\deem\resdata\129121c.r96

Chemical name: Fipronil

RfD(Chronic): .0002 mg/kg bw/day NOEL(Chronic): .019 mg/kg bw/day

RfD(Acute): .02 mg/kg bw/day NOEL(Acute): 2 mg/kg bw/day

Date created/last modified: 05-20-1999/14:45:23/8 Program ver. 6.77

Comment: FQPA SF=1, UF=100, therefore RfD=PAD; Fipronil (+2 metabolites) w/out MB46513

| | Crop | | RESIDUE | | Adj.Fac | | |
|------|------|--|-----------|-----|---------|-------|--------------------------|
| Code | Grp | Food Name | (ppm) | # | #1 | #2 | |
| 291 | 0 | Cottonseed-meal | 0.006000 | 0 | 1.000 | | New, S18, AR |
| 290 | 0 | Cottonseed-oil | 0.006000 | Ō | 1.000 | | New, S18, AR |
| 323 | M | Beef-dried | 0.000740 | 0 | 1.920 | | New, TLT + 0.46, AR |
| 324 | M | Beef-fat w/o bones | 0.006600 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 325 | M | Beef-kidney | 0.000480 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 327 | М | Beef-lean (fat/free) w/o bones | 0.000740 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR |
| 326 | M | Beef-liver | 0.002000 | 0 | 1.000 | 1.000 | New, $TLT + 1.0$, AR |
| 321 | M | Beef-meat byproducts | 0.000480 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 322 | M | Beef-other organ meats | 0.000480 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR |
| 330 | M | Goat-fat w/o bone | 0.006600 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 331 | M | Goat-kidney | 0.000480 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 333 | M | Goat-lean (fat/free) w/o bone | 0.000740 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR |
| 332 | M | Goat-liver | 0.002000 | 0 | 1.000 | 1.000 | New, $TLT + 1.0$, AR |
| 328 | M | Goat-meat byproducts | 0.000480 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR |
| 329 | M | Goat-other organ meats | 0.000480 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR |
| 334 | M | Horsemeat | 0.000740 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR |
| 344 | M | Pork-fat w/o bone | 0.001500 | 0 | 1.000 | 1.000 | New, TLT +0.03 ppm |
| 345 | M | Pork-kidney | 0.000110 | 0 | 1.000 | 1.000 | AR |
| 347 | М | Pork-lean (fat free) w/o bone | 0.000170 | 0 | 1.000 | 1.000 | AR |
| 346 | M | Pork-liver | 0.000440 | 0 | 1.000 | 1.000 | AR |
| 342 | Μ | Pork-meat byproducts | 0.000116 | 0 | 1.000 | 1.000 | AR |
| 343 | M | Pork-other organ meats | 0.000110 | 0 | 1.000 | 1.000 | AR |
| 338 | M | Pork-liver Pork-meat byproducts Pork-other organ meats Sheep-fat w/o bone Sheep-kidney | 0.006600 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 339 | M | Sheep-kidney | 0.000480 | 0 | 1.000 | | New, TLT + 0.26 , AR |
| 341 | M | Sheep-lean (fat free) w/o bone | 0.000740 | 0 | 1.000 | 1.000 | New, $TLT + 0.46$, AR |
| 340 | M | Sheep-liver | 0.002000 | 0 | 1.000 | 1.000 | New, $TLT + 1.0$, AR |
| 336 | M | Sheep-meat byproducts | 0.000480 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR |
| 337 | M | Sheep-other organ meats | -0.000480 | 0 | 1.000 | | New, $TLT + 0.26$, AR |
| 429 | M | Veal-dried | 0.000740 | . 0 | 1.920 | 1.000 | New, $TLT + 0.46$, AR |
| 424 | M | Veal-fat w/o bones | | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, AR |
| 426 | M | Veal-kidney | 0.000480 | 0 | 1.000 | | New, $TLT + 0.26$, AR |
| 425 | M | Veal-lean (fat free) w/o bones | 0.000740 | 0 | 1.000 | 1.000 | New, TLT $+$ 0.46, AR |

```
427 M
         Veal-liver
                                                                        1.000 New, TLT + 1.0, AR
                                               0.002000
                                                                1.000
430 M
         Veal-meat byproducts
                                               0.000480
                                                                1,000
                                                                        1.000 \text{ New, TLT} + 0.26. \text{ AR}
428 M
         Veal-other organ meats
                                               0.000480
                                                                1.000
                                                                        1,000 New, TLT + 0.26, AR
366 P
         Chicken-byproducts
                                               0.000710
                                                                        1.000 \text{ New, TLT + 0.02, AR}
                                                                1.000
368 P
         Chicken-fat w/o bones
                                               0.001900
                                                                1,000
                                                                        1,000 New, TLT + 0.06, AR
367 P
         Chicken-giblets(liver)
                                               0.000710
                                                                1.000
                                                                        1.000 \text{ New, TLT + 0.02, AR}
385 P
         Chicken-giblets (excl. liver)
                                               0.000710
                                                                1.000
                                                                        1.000 \text{ New. TLT} + 0.02. \text{ AR}
369 P
         Chicken-lean/fat free w/o bones
                                               0.000210
                                                                1,000
                                                                        1.000 AR
364 P
         Eggs-white only
                                               0.001100
                                                                1.000
                                                                        1.000 \text{ New, TLT + 0.03, AR}
363 P
         Egas-whole
                                               0.001100
                                                                1,000
                                                                        1.000 New, TLT + 0.03, AR
365 P
         Eggs-volk only
                                               0.001100
                                                                1,000
                                                                        1.000 \text{ New, TLT + 0.03, AR}
         Poultry-other-fat w/o bones
362 P
                                                                        1.000 \text{ New, TLT + 0.06, AR}
                                               0.001900
                                                                1.000
361 P
         Poultry-other-giblets(liver)
                                               0.000710
                                                                1.000
                                                                        1.000 \text{ New. TLT + 0.02. AR}
360 P
         Poultry-other-lean (fat free) w/
                                                                1,000
                                               0.000210
                                                                        1.000 AR
355 P
         Turkey-byproducts
                                               0.000035
                                                                1.000
                                                                        1.000 New, TLT + 0.06, AR
357 P
         Turkev--fat w/o bones
                                               0.001900
                                                                1,000
                                                                        1.000 AR
356 P
         Turkev-giblets (liver)
                                               0.000710
                                                                1.000
                                                                        1.000 \text{ New, TLT + 0.02, AR}
358 P
         Turkey- lean/fat free w/o bones
                                               0.000210
                                                                1,000
                                                                        1.000 AR
449 P
         Turkey-other organ meats
                                               0.000710
                                                                1.000
                                                                        1.000 \text{ New, TLT + 0.02, AR}
319 D
         Milk-fat solids
                                               0.017000
                                                                1.000
                                                                        1.000 New, TLT + 10.5, AR
267 15
         Corn grain-bran
                                               0.015000
                                                                1.000
                                                                        0.070 AR
266 15
         Corn grain-endosperm
                                                               1.000
                                               0.015000
                                                                        0.070 AR
289 15
         Corn grain-oil
                                               0.015000
                                                                1.000
                                                                        0.070 AR
         Corn grain/sugar/hfcs
268 15
                                               0.015000
                                                                1.500
                                                                        0.070 AR
         Corn grain/sugar-molasses
388 15
                                               0.015000
                                                                1.500
                                                                        0.070 AR
408 15
         Rice-bran
                                               0.015000
                                                                1.000
                                                                        0.110 AR
         Rice-milled (white)
271 15
                                               0.015000
                                                                1.000
                                                                        0.110 AR
                                                           0
270 15
         Rice-rough (brown)
                                               0.015000
                                                                1.000
                                                                        0.110 AR
```

Attachment 4: Chronic Exposure Analysis (Fipronil + MB45950 and MB46136)

U.S. Environmental Protection Agency Ver. 6.76 DEEM Chronic analysis for FIPRONIL (1989-92 data) Residue file name: C:\deem\resdata\129121c.r96 Adjustment factor #2 used. Analysis Date 06-02-1999/07:00:35 Residue file dated: 06-02-1999/06:57:30/8 Reference dose (RfD, CHRONIC) = .0002 mg/kg bw/day

COMMENT 1: FQPA SF=1, UF=100, therefore RfD=PAD; Fipronil (+2 metabolites) w/out MB46513

Total exposure by population subgroup

| Population Subgroup | mg/kg body wt/day | Percent of Rfd | | | | | |
|------------------------------------|----------------------|-------------------|--|--|--|--|--|
| U.S. Population (total) | 0.000010 | 4.9% | | | | | |
| U.S. Population (spring season) | 0.000010 | 4.9% | | | | | |
| U.S. Population (summer season) | 0.000010 | 4.9% | | | | | |
| U.S. Population (autumn season) | | 5.1% | | | | | |
| U.S. Population (winter season) | 0.000009 | 4.7% | | | | | |
| Northeast region | 0.000010 | 5.1% | | | | | |
| Midwest region | 0.000010 | 5.1% | | | | | |
| Southern region | 0.000010 | 4.8% | | | | | |
| Western region | 0.000010 | 4.8% | | | | | |
| Hispanics | 0.000011 | 5.5% | | | | | |
| Non-hispanic whites | 0.000010 | 4.8% | | | | | |
| Non-hispanic blacks | 0.000010 | 5.0% | | | | | |
| Non-hisp/non-white/non-black) | 0.000011 | 5.3% | | | | | |
| All infants (< 1 year) | 0.000011 | 5.4% | | | | | |
| Nursing infants | 0.00003 | 1.6% | | | | | |
| Non-nursing infants | 0.000014 | 7.0% | | | | | |
| Children 1-6 yrs | 0.000027 | 13.3% | | | | | |
| Children 7-12 yrs | 0.000016 | 8.2% | | | | | |
| Females 13-19(not preg or nursing) | 0.000009 | 4.6% | | | | | |
| Females 20+ (not preg or nursing) | 0.000006 | 3.0% | | | | | |
| Females 13-50 yrs | 0.000007 | 3.5% | | | | | |
| Females 13+ (preg/not nursing) | 0.000008 | 4.1% | | | | | |
| Females 13+ (nursing) | 0.000009 | 4.3% | | | | | |
| Males 13-19 yrs | 0.000011 | 5.5% | | | | | |
| Males 20+ yrs | 0.000007 | 3.6% | | | | | |
| Seniors 55+ | 0.000006 | 2.8% | | | | | |
| Pacific Region | 0.000010 | 4.8% | | | | | |

Attachment 5: Residue Information - Chronic (MB46513)

Filename: C:\deem\resdata\129121cMB46513.r96

Chemical name: MB46513 (metabolite of fipronil)

RfD(Chronic): .00002 mg/kg bw/day NOEL(Chronic): .0019 mg/kg bw/day

RfD(Acute): .02 mg/kg bw/day NOEL(Acute): 2 mg/kg bw/day

Date created/last modified: 05-20-1999/14:49:05/8

Program ver. 6.77

Comment: FQPA SF=1, UF=100, therefore RfD=PAD; MB46513

| Food Crop | | | RESIDUE | RDF | Adj.Factors | | Comment | | |
|-----------|---|--------------------------------|----------|-----|-------------|-------|--------------------------|----|--|
| | _ | Food Name | (ppm) | # | | #2 | | | |
| 291 | | Cottonseed-meal | 0.004700 | 0 | 1.000 | | New, S18, AR | | |
| 290 | 0 | Cottonseed-oil | 0.004700 | 0 | 1.000 | | New, S18, AR | | |
| 323 | М | Beef-dried | 0.000069 | 0 | 1.920 | 1.000 | New, $TLT + 0.46$, AR | | |
| 324 | Μ | Beef-fat w/o bones | 0.000610 | 0 | 1.000 | | New, TLT + 3.2 ppm, A | ٩R | |
| 325 | M | Beef-kidney | 0.000045 | 0 | 1.000 | | New, $TLT + 0.26$, AR | | |
| 327 | M | Beef-lean (fat/free) w/o bones | 0.000069 | 0 | 1.000 | 1.000 | New, TLT $+$ 0.46, AR | | |
| 326 | M | Beef-liver | 0.000180 | 0 | 1.000 | 1.000 | New, $TLT + 1.0$, AR | | |
| 321 | M | Beef-meat byproducts | 0.000045 | 0 | 1.000 | 1.000 | New, TLT + 0.26 , AR | | |
| 322 | М | Beef-other organ meats | 0.000045 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR | | |
| 330 | M | Goat-fat w/o bone | 0.000610 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, A | łВ | |
| 331 | M | Goat-kidney | 0.000045 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR | | |
| 333 | M | Goat-lean (fat/free) w/o bone | 0.000081 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR | | |
| 332 | M | Goat-liver | 0.000180 | 0 | 1.000 | 1.000 | New, $TLT + 1.0$, AR | | |
| 328 | M | Goat-meat byproducts | 0.000045 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR | | |
| 329 | M | Goat-other organ meats | 0.000045 | 0 | 1.000 | 1.000 | New, $TLT + 0.26$, AR | | |
| 334 | M | Horsemeat | 0.000069 | 0 | 1.000 | 1.000 | New, $TLT + 0.46$, AR | | |
| 344 | M | Pork-fat w/o bone | 0.000310 | 0 | 1.000 | 1.000 | New, TLT +0.03 ppm, A | ЯR | |
| 345 | М | Pork-kidney | 0.000023 | 0 | 1.000 | 1.000 | AR | | |
| 347 | Μ | Pork-lean (fat free) w/o bone | 0.000035 | 0 | 1.000 | 1.000 | AR | | |
| 346 | М | Pork-liver | 0.000092 | 0 | 1.000 | 1.000 | AR | | |
| 342 | М | Pork-meat byproducts | 0.000023 | 0 | 1.000 | 1.000 | AR | | |
| 343 | M | Pork-other organ meats | 0.000023 | 0 | 1.000 | 1.000 | AR | | |
| 338 | M | Sheep-fat w/o bone | 0.000610 | 0 | 1.000 | 1.000 | New, TLT + 3.2 ppm, A | λR | |
| 339 | М | Sheep-kidney | 0.000045 | 0 | 1.000 | 1.000 | New, TLT $+$ 0.26, AR | | |
| 341 | M | Sheep-lean (fat free) w/o bone | 0.000069 | 0 | 1.000 | 1.000 | New, TLT + 0.46, AR | | |
| 340 | M | Sheep-liver | 0.000180 | 0 | 1.000 | 1.000 | New, TLT + 1.0, AR | | |
| 336 | M | Sheep-meat byproducts | 0.000045 | 0 | 1.000 | 1.000 | New, TLT + 0.26 , AR | | |
| 337 | M | Sheep-other organ meats | 0.000045 | 0 | 1.000 | 1.000 | New, TLT + 0.26 , AR | | |
| 429 | М | Veal-dried | 0.000069 | 0 | 1.920 | 1.000 | New, TLT + 0.46, AR | | |
| 424 | Μ | Veal-fat w/o bones | 0.000610 | 0 | 1.000 | 1.000 | New, TLT $+$ 3.2 ppm, A | łВ | |
| 426 | M | Veal-kidney | 0.000045 | 0 | 1.000 | 1.000 | New, TLT + 0.26, AR | | |
| 425 | M | Veal-lean (fat free) w/o bones | 0.000069 | 0 | 1.000 | 1.000 | New, TLT + 0.46 , AR | | |
| 427 | М | Veal-liver | 0.000180 | 0 | 1.000 | 1.000 | New, TLT + 1.0 , AR | | |

| 430 | M | Veal-meat byproducts | 0.000045 | 0 | 1.000 | 1.000 New, | TLT + 0.26, AR |
|-----|----|----------------------------------|----------|-----|-------|------------|------------------|
| 428 | Μ | Veal-other organ meats | 0.000045 | 0 | 1.000 | 1.000 New, | TLT + 0.26, AR |
| 366 | P | Chicken-byproducts | 0.000036 | 0 | 1.000 | 1.000 New, | TLT + 0.02, AR |
| 368 | P | Chicken-fat w/o bones | 0.000098 | 0 | 1.000 | 1.000 New, | TLT + 0.06, AR |
| 367 | P | Chicken-giblets(liver) | 0.000036 | 0 | 1.000 | | TLT + 0.02, AR |
| 385 | P | Chicken-giblets (excl. liver) | 0.000036 | 0 | 1.000 | 1.000 New, | TLT + 0.02, AR |
| 369 | P | Chicken-lean/fat free w/o bones | 0.000010 | 0 | 1.000 | 1.000 AR | |
| 364 | P | Eggs-white only | 0.000055 | 0 | 1.000 | 1.000 New, | TLT + 0.03, AR |
| 363 | P | Eggs-whole | 0.000055 | 0 | 1.000 | 1.000 New, | TLT + 0.03, AR |
| 365 | P | Eggs-yolk only | 0.000055 | 0 | 1.000 | 1.000 New, | TLT + 0.03, AR |
| 362 | P | Poultry-other-fat w/o bones | 0.000098 | 0 | 1.000 | 1.000 New, | TLT + 0.06, AR |
| 361 | P | Poultry-other-giblets(liver) | 0.000036 | 0 | 1.000 | 1.000 New, | TLT + 0.02, AR |
| 360 | P | Poultry-other-lean (fat free) w/ | 0.000010 | 0 | 1.000 | 1.000 AR | |
| 355 | P | Turkey-byproducts | 0.000036 | 0 | 1.000 | 1.000 New, | TLT + 0.06, AR |
| 357 | P | Turkeyfat w/o bones | 0.000098 | . 0 | 1.000 | 1.000 AR | |
| 356 | Ρ | Turkey-giblets (liver) | 0.000036 | 0 | 1.000 | 1.000 New, | TLT + 0.02, AR |
| 358 | P | Turkey- lean/fat free w/o bones | 0.000010 | 0 | 1.000 | 1.000 AR | |
| 449 | P | Turkey-other organ meats | 0.000036 | 0 | 1.000 | 1.000 New, | TLT + 0.02, AR |
| 319 | D | Milk-fat solids | 0.001900 | 0 | 1.000 | 1.000 New, | TLT + 10.5, AR |
| 408 | 15 | Rice-bran | 0.005000 | 0 | 1.000 | 0.110 AR | |
| 271 | 15 | Rice-milled (white) | 0.005000 | 0 | 1.000 | 0.110 AR | |
| 270 | 15 | Rice-rough (brown) | 0.005000 | 0 | 1.000 | 0.110 AR | |

Attachment 6: Chronic Exposure Analysis (MB46513 only)

U.S. Environmental Protection Agency Ver. 6.76 DEEM Chronic analysis for MB46513 (METABOLITE OF FIPRONIL) (1989-92 data) Residue file name: C:\deem\resdata\129121cMB46513.r96

Adjustment factor #2 used. Analysis Date 06-02-1999/07:05:26 Residue file dated: 06-02-1999/07:04:57/8 Reference dose (RfD, CHRONIC) = .00002 mg/kg bw/day

COMMENT 1: FQPA SF=1, UF=100, therefore RfD=PAD; MB46513

Total exposure by population subgroup

| | Total Exposure | | | | | |
|---|--|---------------------------------------|--|--|--|--|
| Population Subgroup | mg/kg body wt/day | Percent of Rfd | | | | |
| U.S. Population (total) | 0.000001 | 4.9% | | | | |
| U.S. Population (spring season) U.S. Population (summer season) U.S. Population (autumn season) U.S. Population (winter season) | 0.000001 0.000001 0.000001 0.000001 | 5.0% 4.9% 5.1% 4.7% | | | | |
| Northeast region Midwest region Southern region Western region | 0.000001 0.000001 0.000001 0.000001 | 5.3% 5.0% 4.8% 4.8% | | | | |
| Hispanics Non-hispanic whites Non-hispanic blacks Non-hisp/non-white/non-black) | 0.000001 0.000001 0.000001 0.000001 | 5.9% 4.8% 5.1% 6.1% | | | | |
| All infants (< 1 year) Nursing infants Non-nursing infants Children 1-6 yrs Children 7-12 yrs | 0.000001 0.000000 0.000002 0.000003 0.000002 | 5.8% 1.6% 7.5% 13.4% 8.1% | | | | |
| Females 13-19(not preg or nursing) Females 20+ (not preg or nursing) Females 13-50 yrs Females 13+ (preg/not nursing) Females 13+ (nursing) | 0.000001 0.000001 0.000001 0.000001 0.000001 | 4.5% 3.0% 3.5% 4.1% 4.5% | | | | |
| Males 13-19 yrs Males 20+ yrs Seniors 55+ Pacific Region | 0.000001 0.000001 0.000001 0.000001 | 5.2% 3.7% 2.8% 4.9% | | | | |



002346

Chemical:

Fipronil

PC Code:

129121

HED File Code

147141

Memo Date:

11000 Chemistry Reviews

File ID:

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Accession Number:

DPD255832

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